

## **REMARKS**

This Reply is responsive to an Office Action in this case mailed on June 2, 2005. In the Office Action, the Examiner rejected claims 2-14, 21, and 22 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement; and rejected claims 2-25 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,010,475 to Thomas et al. (Thomas) in view of U.S. Patent No. 5,840,190 to Scholander et al. (Scholander).

By this Reply, claims 2-14, 21, and 22 have been cancelled without prejudice or disclaimer of the subject matter thereof, claims 15 and 18-20 have been amended, and claims 26-29 have been added to cover additional features of the present invention. Claims 15-20 and 23-29 are pending in the above-captioned patent application. Prompt consideration of this Reply and allowance of the application are earnestly requested.

New claim 26 recites, among other things, "bringing [a cationic polymer] solution in contact with a semipermeable membrane" before "purging the exchanger of the solution." New claim 26 further recites "bringing a solution [containing an anticoagulant agent] in contact with the semipermeable membrane" before "purging the exchanger of the solution." The claim also recites "sterilizing the exchanger when the semipermeable membrane based on polyacrylonitrile carrying anionic or anionizable groups is coated with the cationic polymer and the anticoagulant agent."

At the outset, Applicants respectfully note that the Examiner's rejections of claims 2-14, 21, and 22 under 35 U.S.C. § 112, first paragraph, are moot in light of Applicants' cancellation of these claims.

Applicants respectfully traverse the Examiner's rejection of claims 2-25 under 35 U.S.C. § 103(a) as being unpatentable over Thomas in view of Scholander. Applicants respectfully submit that the Examiner's rejections of claims 2-14, 21, and 22 under 35 U.S.C. § 103 are also moot in light of Applicants' cancellation of these claims.

To the extent the Examiner's rejections under 35 U.S.C. § 103(a) are understood, Applicants note that in order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine teachings of the references. Second, there must be a reasonable expectation of success. Finally, the prior art references, when combined, must teach or suggest all the claim limitations. See M.P.E.P. § 2143. Applicants respectfully submit that the Examiner failed to establish a *prima facie* case of obviousness.

Insofar as the Examiner's rejections under 35 U.S.C. § 103(a) are relevant to pending claims 15-20 and 23-25 and new claims 26-29, Applicants respectfully submit that new claim 26, for example, is not obvious over Thomas in view of Scholander, because neither Thomas nor Scholander teaches or suggests a method comprising the subsequent steps of "bringing [a cationic polymer] solution in contact with a semipermeable membrane" before "purging the exchanger of the [cationic polymer] solution," "bringing a solution [containing an anticoagulant agent] in contact with the semipermeable membrane" before "purging the exchanger of the solution [containing an anticoagulant agent]," and "sterilizing the exchanger when the semipermeable

membrane based on polyacrylonitrile carrying anionic or anionizable groups is coated with the cationic polymer and the anticoagulant agent.”

Thomas teaches that a drop of cationic polymer, for example polyethyleneimine (PEI), is “deposited in each small tube for access to the blood compartment, after which the tubes for access to the two compartment of the dialyser were closed.” Col. 7, lines 57-63. The dialyser is then “sterilized with ethylene oxide.” *Id.* Due to the cationic solution, the “biocompatible surface does not run the risk of being damaged by highly energetic sterilization.” Col. 3, lines 38-40. Thus, Thomas teaches sterilization in the presence of the cationic solution.

Claim 26, however, requires “purging the exchanger of the solution containing the cationic polymer” followed by “sterilizing the exchanger.” Accordingly, Thomas teaches away from the method recited in claim 26.

The Examiner alleges that Scholander discloses a “heparin coated membrane.” Office Action at page 4. However, Scholander is silent as to the claimed sterilizing and certainly fails to teach “purging the exchanger of the [cationic polymer] solution,” before sterilization, as further required by new claim 26. Scholander, therefore, fails to overcome the above-noted deficiencies of Thomas.

Moreover, Applicants respectfully disagree with the Examiner’s assertion that it would be obvious to rearrange the sequence of process steps disclosed in Thomas and Scholander. Office Action at page 5. None of the cases cited by the Examiner (Office Action at 5-6) are relevant because in each case, the changing of the order of process steps did not effect the outcome of the process in any relevant, new, or unexpected way, nor was there a reason for changing the order of the process steps, as there is

here. As noted above, Thomas expressly teaches applying the cation polymer solution to prevent the underlying surface during sterilization. Col. 3, lines 38-40, Col. 5, lines 57-63. Scholander, on the other hand, is silent as to sterilization of any kind. Moreover, Applicants advise that even if one of ordinary skill would sterilize the biocompatible membrane of Scholander (and Applicants disagree that one of ordinary would necessarily do so in light of the Scholander disclosure), such sterilization would occur after manufacturing has been completed, not in the presence of the cationic solution. Accordingly, at best Thomas and Scholander teach away from one another, and these references are not combinable in the manner proposed by the Examiner.

Thus, for at least the above reasons, new claim 26 is allowable over Thomas in view of Scholander, and new claims 27-29 are allowable at least due to their dependence from claim 26. Additionally, pending claims 15-20 and 23-25 are allowable for at least the reasons give above with respect to new claim 26. For example, Thomas and Scholander teach away from one another and cannot be combined to render these claims obvious. Accordingly, Applicants respectfully request that the Examiner withdraw all rejections and allow the pending claims.

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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